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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,668	10/02/2003	Gary Jay Morris	73/.64	1054

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Gary J. Morris
2026 Glenmark Avenue
Morgantown, WV 26505-2900

EXAMINER	
GISHNOCK, NIKOLAI A	
ART UNIT	**PAPER NUMBER**
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/677,668	MORRIS, GARY JAY	
	Examiner	Art Unit	
	Nikolai A. Gishnock	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,13-23 and 25-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,13-23 and 25-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *02 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the Applicant's remarks, filed 5/10/2006, claims 5, 12, & 24 are cancelled. Claims 1-4, 6-11, 13-23, & 25-57 are pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4, 6-11, 13-18, 39-41, 48-50, & 53 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fails to disclose the nature of the interface of the electronic control unit with the fluid pressure control element to maintain periodic and simulated systolic and diastolic pressure levels in a vessel, nor the nature of the interface between an automatic sphygmomanometer and the Applicant's instant invention that receives blood pressure and pulse rate data to maintain said pressure.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Pickering et al. (US 6,168,567), hereinafter known as Pickering.

- Pickering discloses an apparatus for simulating human blood pressure cycles and providing a tactile interface (sphygmomanometer with conventional squeeze bulb, Column 3, Lines 28-31) [Claim 1];
- Pickering discloses an element to generate pressurized fluid (air bladder, Column 3, Lines 28-31 and Figure 1, Element 14) [Claim 1];
- Pickering discloses a pressure vessel containing the pressurized fluid whereby a human can sense, by touch, pressure amplitudes within the vessel (arm cuff with an inflatable air bladder, Column 2, Lines 59-62 and Figure 1, Element 12) [Claim 1];
- Pickering discloses a fluid pressure control element to control pressure levels within the pressure vessel (air outlet valve for deflating the air bladder, Column 2, Lines 63-64) [Claim 1];

- Pickering discloses an electronic control unit (Figure 2, Element 46) to interface with the fluid pressure control element (Figure 2, Elements 280 & 290) to maintain periodic, simulated systolic and diastolic blood pressure levels within the pressure vessel (electronic control includes closed-loop feedback circuit for adjusting an electro-mechanical air valve in dependence on the instantaneous cuff pressure, Column 4, Lines 20-24) [Claim 1].
- Pickering discloses a pressure vessel comprising an arm cuff with inflatable air bladder (Figure 1, Element 12), whereby the periodic, simulated blood pressure levels inside the cuff are sensed by human touch [Claim 13].

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

    1. Determining the scope and contents of the prior art.
    2. Ascertaining the differences between the prior art and the claims at issue.
    3. Resolving the level of ordinary skill in the pertinent art.
    4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-4, 6, 10, 14, 15, 18-21, 23, 26, 28-31, 35-42, 44, 46, 48, 50-54, 56, & 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futcher et al. (US 5,772,413), hereinafter known as Futcher.

- Futcher discloses a medical demonstration apparatus for simulating normal or abnormal human blood pressure cycles (improving awareness of high blood pressure and hypertension, Column 6, Lines 40-42) and providing a tactile interface (bulb able to be squeezed, Abstract) [Claims 1, 19, 29, 39, 42 & 57];
- Futcher discloses a method for conveying, by touch, to a human subject, a level of pressure within a pressurized vessel provides contrast between the effort required to replicate normal blood pressure and high blood pressure, Column 4, Lines 56-60) [Claim 36];
- Futcher discloses an element to generate pressurized fluid (air is forced out of and into the bulb, Column 3, Lines 56-57 and Figure 1, Element 3) [Claims 1, 19, 29, 36, 39 & 57];
- Futcher discloses a pressure vessel or chamber containing the pressurized fluid whereby a human can sense, by touch, periodic pressure amplitudes or magnitudes or levels within the vessel, or pressurized fluid acting upon a movable surface (patient gauges the normal requirements of cardiac exertion through the effort required to squeeze the bulb, Column 4, Lines 11-13) [Claims 1, 19, 29, 36, & 39];
- Futcher discloses a fluid pressure control element to control pressure levels within the pressure vessel (Figures 14-17, Elements 15 {resistor}, 21 {variable

restrictor}, 23 {one-way valve} & 25 {bleed line restrictor}) [Claims 1, 29, 39, & 57];

- Futcher discloses a pressure vessel containing at least one movable or distendable surface (Figures 1-3, Element 3) [Claims 4, 19, 29, & 39];
- Futcher discloses periodic pressure amplitudes comprising at least one normal and at least one abnormal human blood pressure in the pressure vessel (contrast between replicating normal and high blood pressure of a patient, Column 4, Lines 56-60; shaped to resemble a human heart, Column 3, Line 54) [Claims 19, 29, & 57];
- Futcher discloses periodic pressure amplitudes comprising at least one human systolic and diastolic pressure level (level at cycle stage simulates diastolic pressure, Column 4, Lines 39-41) [Claim 29];
- Futcher discloses where the pressure vessel comprises an elastomeric hollow bulb that can be held in a human hand, and internal pressure amplitudes of fluid within the bulb are sensed by human touch (patient manually squeezes the bulb to create pressure on the manometer, Column 4, Lines 1-3) [Claims 10 & 23];
- Futcher discloses where the pressure vessel comprises an elastic-walled closed tube whereby the periodic simulated blood pressure levels inside the tube are sensed by human touch or gripping of the tube (bulb is made from molded plastic and resembles a human heart, Column 3, Lines 52-54) [Claims 14 & 26];

- Futcher discloses whereby a human can physically feel a pressure level of the pressurized fluid within the elastomeric hollow bulb by gripping the bulb (Column 4, Lines 1-3 and 11-14) [Claim 57];
- Futcher discloses a visual indicator to display indicia which specify pressure amplitudes or magnitudes within the pressure vessel or elastomeric hollow bulb (Figure 1, Element 2 {manometer}) [Claims 19 & 42];
- Futcher discloses a visual pressure level indicator comprising an analog pressure gage (Figure 1, Element 2 {manometer}) [Claims 28 & 35];
- Futcher discloses indicating on a visual display the pressure level of a pressurized fluid (Figure 1, Element 2 {manometer}; pumping action on the bulb causes a normal cyclical blood pressure reading indicated on the manometer, Column 4, Lines 8-11) [Claim 56];
- Futcher discloses where the fluid is a gas (Column 3, Lines 56-57) [Claims 2, 20, 30, 37, & 40].
- Futcher discloses where the fluid is a substantially segregated mixture of a liquid and a gas (liquid in manometer, Figure 1, Element 2) [Claims 3, 21, 31, 38, & 41]
- Futcher discloses at least one pressure sensor to determine the pressure level within the pressure vessel (manometer, Figure 1, Element 2) [Claim 6];
- Futcher discloses at least one user-operable control to set pressure excursion parameters, or select minimum and maximum limits of pressures within the pressure vessel to simulate systolic and diastolic blood pressure levels (Figures 18-20, Elements 114 & 115 {restrictors}) [Claims 15, 44, 46, & 48];

- Futcher discloses a user-operated control to switch at least the simulated human systolic and diastolic blood pressure amplitudes between normal and abnormal blood pressure cycles or values (Figures 18-20, Elements 114 & 115 {restrictors}) [Claims 50-54];
- Futcher discloses systolic and diastolic blood pressure level data used to set the minimum and maximum amplitude of cyclic pressure levels within the pressure vessel (Figures 18-20, Elements 114 & 115 {restrictors}) [Claim 18];
- Futcher discloses a control unit to interface with the fluid pressure element to maintain periodic, simulated systolic and diastolic blood pressure levels within the vessel. However, the only difference between the control unit as disclosed by Futcher and the instant invention is the use of an automatic electronic control unit. It is well established that broadly providing an automatic or mechanical means to replace a manual activity, which accomplishes the same result, is not sufficient to distinguish over the prior art (*In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), See MPEP 2144.04 III). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included an electronic control unit to the invention of Futcher to more precisely control the simulation to achieve a more accurate and lifelike blood pressure [Claims 1, 19, 29, 39, 42 & 57].

4. Claims 7-9, 17, 22, 25, 27, 32-34, & 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futcher, in view of claims 1, 19, & 29 above, and further in view of Pickering.

- Futcher discloses a hollow elastomeric bulb to pressurize fluid by manual compression and providing a tactile interface to a human subject for sensing fluid pressure magnitudes internal to the bulb, by gripping with at least one hand [Claims 1, 19, & 29]. What Futcher fails to teach is a second hollow elastomeric bulb or arm cuff pneumatically connected to a first bulb such that the pressure in the second bulb is controlled by the amount of manual compression of the first bulb. However, Pickering teaches a sphygmomanometer comprising an arm cuff with inflatable air bladder, and a pumping device for inflating the air bladder (Column 2, Lines 59-62), wherein the pumping device for inflating the air bladder may be a conventional squeeze bulb, as used in conventional sphygmomanometers, or an electrically operated pump (Column 3, Lines 28-31). Therefore, It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have incorporated the manual pumping device, electric pump, inflatable cuff, and pneumatic connections of Pickering with the medical demonstration device of Futcher, in order to utilize the advantages of an inexpensive and accurate sphygmomanometer with a medical demonstration device [Claims 9, 22, 25, 32, 33, & 42].
- Futcher discloses a fluid pressure control element to control pressure levels within the pressure vessel [Claim 1]. What Futcher fails to teach is the fluid

pressure control element being a comprising an electro-mechanically actuated pressure regulator, or an electric solenoid control valve system. However, Pickering teaches an air outlet valve for the air bladder comprising an electrically actuated valve (Column 3, Lines 40-51). Therefore, it would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to have incorporated the electrically operated valve of Pickering with the elastomeric bulb of Futcher, in order to automate the manual activity of regulating the pressurized air in the pneumatic system [Claims 7 & 8].

- Futcher teaches a visual indicator to display indicia, which specify pressure amplitudes within the pressure vessel [Claim s 19 & 42]. What Futcher fails to teach is the visual indicator comprising an electronic digital display. However, Pickering teaches an LCD display, displaying instantaneous pressure in the air bladder (Figure 1, Element 22; Column 3, Lines 12-16). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have incorporated the electronic digital blood pressure display of Pickering with the medical demonstration device of Futcher, in order to reduce the difficulty of reading a standard sphygmomanometer's dial gage [Claims 27 & 34.
- Futcher teaches a control unit to interface with a pressure control element to maintain periodic simulated systolic and diastolic blood pressure levels in a pressure vessel [Claim 1]. What Futcher fails to teach is an electronic interface circuit to connect an electronic sphygmomanometer to receive systolic and

diastolic blood pressure level data and pulse rate data as measured. However, Pickering teaches an electrical circuit including a microprocessor, which is capable of determining a pulse rate from the periodic changes in blood pressure, and displaying it on the LCD display (Column 3, Lines 32-39). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have combined the electronic blood pressure and pulse rate interface circuit of Pickering with the medical demonstration device of Futcher, in order to store and process the data via a digital computer [Claim 17].

5. Claims 16, 45, 47, & 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futcher, in view of claims 1, 19, & 29 above, and Pickering, in view of claims 15, 44, 46, & 48 above, and further in view of Baldwin (US 4,773,865), hereinafter known as Baldwin.

- Futcher teaches a user-operable control to set the pressure excursion rates parameters within the pressure vessel [Claims 15, 44, 46, & 48]. Pickering teaches an electrical circuit providing digital signals representing the systolic and diastolic pressures and pulse rates for use by a computer for storage and processing [Claims 1 & 17]. What Futcher and Pickering fail to explicitly teach is a user-operable control to set a simulated cardiac pulse rate for the simulated human blood pressure cycles. However, Baldwin teaches a medical demonstration device with flexible plastic veins and arteries, and a bulb syringe fluidly connected to the simulated femoral artery such that a pulse may be simulated (Column 3, Lines 66-68 and Column 4, Lines 1-28). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have connected the manual pump means of Pickering to the medical demonstration apparatus of Futcher, in the manner prescribed by Baldwin, in order to assist a student in locating a blood vessel by sensory feedback [Claims 16, 45, 47, & 49].

6. Claims 11, 43, & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futcher, in view of claims 1, 19, & 29 above, and Pickering, in view of claims 10, 23, & 42 above, and further in view of Frazier (US 6,669,624), hereinafter known as Frazier.

- Futcher teaches a pressure vessel comprising an elastomeric hollow bulb that can be held by gripping in a human hand and wherein the internal pressures are sensed by human touch [Claims 10 & 23]. Pickering teaches a first elastomeric bulb to pressurize fluid in a second elastomeric bulb by manual compression [Claim 42]. What Futcher and Pickering fail to teach is an incompressible, non-liquid member positioned within the second elastomeric hollow bulb such that substantial portions of the internal surfaces of the bulb are held in contact with the incompressible member by manually squeezing the bulb. However, Frazier teaches a heart-assist pump comprising a flexible balloon catheter, inflated and deflated by gas pressure, with an incompressible lumens within the balloon for conveying gas to and from the balloon (Column 6, Lines 7-28 and Figure 2, Elements 8 and 14). Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have fabricated the elastomeric bulb of Futcher, connected to the manual pump means of Pickering, in the structure designed by Frazier, in order to allow the bulb to withstand rapid cyclic inflation and deflation [Claims 11, 43, & 55].

Response to Arguments

7. The declaration under 37 CFR 1.132 and arguments, see pages 17-23, filed 5/10/2006 are insufficient to overcome the rejection of claims 1-4, 6-11, 13-18, 39-41, 48-50, & 53, based upon insufficiency of disclosure under 35 U.S.C. 112, first paragraph, as set forth in the last Office action because: Facts presented are not germane to the rejection at issue. Applicant's arguments and declaration accurately describe the function of the electronic control unit of an automatic sphygmomanometer, but fail to disclose the nature of the separate interface of the electronic control unit within Applicant's instant invention, nor the nature of the interface between the sphygmomanometer and the Applicant's instant invention. The enablement rejection stands because the sufficiency of detail lacking in the specification and the failure to explicitly incorporate by reference literature that discloses the nature of the electronic control unit of Applicant's invention is lacking, and would necessitate undue experimentation for one skilled in the art to make or use the invention. The Applicant is obliged to point out where in the specification support is found for the method or

procedure for how the electronic control unit will interface with the system components, pressurize/depressurize the vessel, or interface with an automatic sphygmomanometer. Furthermore, affidavits or declarations presented to show that the disclosure of an application is sufficient to one skilled in the art are not acceptable to establish facts which the specification itself should recite. In re Buchner, 929 F.2d 660, 18 USPQ2d 1331 (Fed. Cir. 1991). See MPEP 716.08.

8. Applicant's arguments, see pages 17-23, filed 5/10/2006, with respect to claims 19-23, 25-38, & 42-47 have been fully considered and are persuasive. The 35 U.S.C. 112, first paragraph rejection of 4/4/2006, with respect to the pneumatically connected components, has been withdrawn.

9. Applicant's arguments, see pages 24-31, filed 5/10/2006, with respect to claims 1, 4-6, 19, 29, 34, 36, & 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Souma (US 5,467,772) discloses a typical automatic sphygmomanometer.
- Aboud (US 6,790,043) discloses a medical demonstration device for use on a cadaver, which simulated blood pressure and pulse.
- Ramsey III (US 4,036,216) discloses flexible closed tube blood pressure monitor.

- Barker (US 5,201,320) discloses a hybrid sphygmomanometer with a digital display and electronic controller.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai A. Gishnock whose telephone number is 571-272-1420. The examiner can normally be reached on M-F 8:30a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P. Olszewski can be reached on 571-272-6788. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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1/22/2007

Kathleen Mosser
KATHLEEN MOSSER
PRIMARY EXAMINER